

AVAILABILITY OF MODIFIED TEXT

NOTICE IS HEREBY GIVEN that the Dental Board of California has proposed modifications to the text of section 1044, 1044.1, 1044.2, 1044.3, 1044.4 and 1044.5 in Title 16 Cal.Code Reg. which were the subject of a regulatory hearing on May 31, 2006. A copy of the modified text is enclosed. Any person who wishes to comment on the proposed modifications may do so by submitting written comments on or before March 21, 2007 to the following:

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DATED: March 6, 2007

RICHARD L. WALLINDER, JR.
Executive Officer
Dental Board of California

Modified Text

Changes to the originally proposed language are shown by double underline for new text and double strike-through for deleted text .

1044. Definitions

For purposes of this Article and of Articles 2.85 and 2.86 of Chapter 4, of Division 2 of the Code, the terms set forth below shall be defined as follows:

(a) "Outpatient basis" as used in Sections 1647.11 and 1647.19 means all settings where oral conscious sedation is being provided to dental patients with the exception of ~~means a patient under the age of 13 treated in a treatment facility which is not accredited by the Joint Commission on Health Care Organizations or licensed by an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of~~ Division 2 the California Department of Health Services as a "general acute care hospital" as defined in subdivision (a) of Section 1250 of the Health and Safety Code (commencing with section 1248).

~~(b) "Physical evaluation means recording patient age, weight, and general health, along with any known or suspected medically compromising conditions.~~

~~(e)~~ (b) A patient under oral conscious sedation shall be considered "sedated" for that period of time beginning with the administration of oral conscious sedation and continuing until that time when the dental procedures have been completed, and after the maximum effects of all agents have been experienced by the patient.

(c) "Age-appropriate" means under 13 years of age for the oral conscious sedation certificate for minor patients and 13 years or older for the oral conscious sedation certificate for adult patients.

(d) For the purposes of adult oral conscious sedation, administering a drug to a patient in a dose that exceeds the maximum recommended dose as established and listed by the United States Federal Drug Administration (FDA) on the drug's FDA-approved professional labeling insert or packaging information shall be considered to exceed the single maximum dose that can be prescribed for home use.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: 1647.10 and ~~1647.14~~ 1647.18, Business and Professions Code.

1044.1. Requirements, Standards

A dentist ~~shall~~ is not be required to possess an oral conscious sedation certificate if the oral conscious sedation administered to his or her ~~minor~~ patient is directly administered and monitored by a dentist who possesses a general anesthesia permit, a conscious sedation permit, or an oral conscious sedation certificate for a minor patient or is administered by a licensed physician and surgeon who possesses a general anesthesia permit. A dentist who only possesses an adult oral conscious sedation certificate may not

provide oral conscious sedation to a minor patient. Notwithstanding the above However, the office in which the oral conscious sedation is administered shall meet the facilities and equipment standards set forth in Section 1044.5.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Section 1647.10, 1647.11, 1647.18 and 1647.19, Business and Professions Code.

1044.2. Board Approved Programs

(a) For purposes of Section 1647.12(a)(2)(b) and Section 1647.20(b), a post-doctoral program in periodontics, a general practice residency or other advanced education in a general dentistry post-doctoral program approved accredited by the Board Commission on Dental Accreditation that meets the didactic and clinical requirements of Section 1044.3 shall be deemed approved by the board. A dentist must submit a copy of his or her certificate of completion from a board approved educational program as defined in Section 1044.3 or diploma from a recognized dental residency or post-doctoral program as defined in this section ~~evidence of completion of this requirement to the board.~~

Note: Authority cited: Section 1614, Business and Professions Code. Reference: 1647.10, ~~and~~ 1647.12, 1647.18 and 1647.20, Business and Professions Code.

1044.3. Board Approved Education

(a) The goal of an instructional program in oral medications and sedation is to provide the educational opportunity for dentists to receive training in the techniques and skills required to safely and effectively administer oral pharmacologic agents, alone or in combination with nitrous oxide-oxygen inhalation, for the purpose of obtaining conscious sedation in the minor or adult dental patient.

(b) The educational program shall be ~~in a facility~~ approved by the ~~B~~board and shall consist of satisfactory completion of at least 25 hours of instruction including a clinical component utilizing at least one age-appropriate ~~minor~~ patient. The program shall be directed solely toward either the administration of oral conscious sedation to adult patients or the administration of oral conscious sedation to minor patients. The program ~~course~~ shall include but not be limited to, the following areas:

(1) Historical, philosophical, and legal aspects of age-appropriate oral conscious sedation of ~~minor~~ dental patients, including the Business and Professions Code.

(2) Indications and contraindications for the utilization of age-appropriate oral conscious sedation in ~~minor~~ dental patients.

(3) Patient evaluation and selection through a review of the medical history, physical assessment, and medical consultation.

(4) Definitions and characteristics for levels of sedation achieved with oral sedative agents, with special emphasis on the distinctions between conscious sedation,

deep sedation, and general anesthesia as recognized by such organizations as the American Dental Association, the American Academy of Pediatric Dentistry and the ~~B~~oard of Dental Examiners.

(5) Review of respiratory and circulatory physiology and related anatomy, with special emphasis on, and clinical experience in, establishing and maintaining an age-appropriate patent airway in the ~~minor~~ patient.

(6) Pharmacology of agents used in contemporary oral conscious sedation techniques including drug interactions, incompatibilities and side effects and adverse reactions.

(7) Indications, contraindications and technique considerations in the use of different contemporary age-appropriate oral conscious sedation modalities for ~~minor~~ dental patients.

(8) Patient monitoring during all stages of the procedure by clinical observation and appropriate mechanical devices for responsiveness, airway patency, and recording of vital signs.

(9) Importance of and techniques for maintaining proper documentation of the procedure, including aspects of informed consent, pre and post operative instructions, dietary considerations, preoperative health evaluation, rationale for the procedure, baseline and intermittent vital signs, a detailed record of all oral and inhalation drugs administered, the patient response to the drugs, and recovery and discharge criteria.

(10) Prevention, recognition and management of complications and life-threatening situations that may arise during age-appropriate oral conscious sedation of the ~~minor~~ dental patient, including the principles of ~~pediatric~~ advanced life support.

(c) A provider of a course in oral medications and sedation intending to meet the requirements of this section shall submit to the ~~B~~oard an application on form OCS-~~56~~ (rev. 03/07) (~~Rev. 10/99~~), Application for Course Approval for Oral Conscious Sedation incorporated herein by reference. The ~~B~~oard may approve or deny approval of any such course. Approval shall be granted after an evaluation of all components of the course has been performed and such evaluation indicates that the course meets the requirements of this section.

(d) Approval by the ~~B~~oard of a course in oral medications and sedation shall remain in effect for a period of twenty-four months, unless withdrawn sooner, after which a new application for approval must be submitted to the ~~B~~oard.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, ~~and~~ 1647.12, and 1647.20, Business and Professions Code.

1044.4. Documentation of 10 Cases.

(a) For the purposes of Section 1647.20(d), an applicant for an oral conscious sedation certificate for adult patients who has been using oral conscious sedation in connection with the treatment of adult patients shall submit the following documentation

for each of the 10 cases of oral conscious sedation on form OCS-4 (Rev 1/06 03/07)
Documentation of Oral Conscious Sedation Cases incorporated herein by reference.

(1) Patient's sex, age, and weight.

(2) Date of oral conscious sedation procedure.

(3) Type of dental procedure performed and duration of sedation.

(4) A description of the method, amount, and specific oral conscious sedation agent administered.

(5) A statement on how the patient was monitored and by whom.

(6) Patient's condition at discharge.

(b) Applicants shall also provide documentation or patient records, including preoperative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge for each patient.

(c) Applicants shall submit legible copies of the above required information with patient identifying information redacted.

Note: Authority cited: Section 1614, Business and Professions Code. Reference: Sections 1647.10, and 1647.12, 1647.20 and 1647.22, Business and Professions Code.

1044.5. Facility and Equipment Standards.

A facility in which oral conscious sedation is administered to ~~minor~~ patients pursuant to this article shall meet the standards set forth below.

(a) Facility and Equipment.

(1) An operatory large enough to adequately accommodate the patient and permit a team consisting of at least three individuals to freely move about the patient.

(2) A table or dental chair which permits the patient to be positioned so the attending team can maintain the airway, quickly alter patient position in an emergency, and provide a firm platform for the management of cardiopulmonary resuscitation.

(3) A lighting system which is adequate to permit evaluation of the patient's skin and mucosal color and a backup lighting system which is battery powered and of sufficient intensity to permit completion of any treatment which may be underway at the time of a general power failure.

(4) An appropriate functional suctioning device that permits aspiration of the oral and pharyngeal cavities. A backup suction device that can function at the time of general power failure must also be available.

(5) A positive-pressure oxygen delivery system capable of administering greater than 90% oxygen at a 10 liter/minute flow for at least sixty minutes (650 liter "E" cylinder), even in the event of a general power failure. All equipment must be age-appropriate and capable of accommodating ~~minor~~ the patients being seen at the permit-holder's office of all ages and sizes.

(6) Inhalation sedation equipment, if used in conjunction with oral sedation, must have the capacity for delivering 100%, and never less than 25%, oxygen concentration at a flow rate appropriate for an age appropriate ~~minor~~ patient's size, and

have a fail-safe system. The equipment must be maintained and checked for accuracy at least annually.

(b) Ancillary equipment, which must include the following, and be maintained in good operating condition:

(1) Age-appropriate ~~o~~Oral airways capable of accommodating ~~minor~~ patients of all ~~ages and~~ sizes.

(2) An age-appropriate sphygmomanometer with cuffs of appropriate size for ~~minor~~ patients of all ~~ages and~~ sizes.

(3) A precordial/pretracheal stethoscope.

(4) A pulse oximeter.

(c) The following records shall be maintained:

(1) An adequate medical history and physical evaluation, updated prior to each administration of oral conscious sedation. Such records shall include, but are not limited to, an assessment including at least visual examination of the airway, the age, sex, weight, risk assessment physical status (American Society of Anesthesiologists Classification), and rationale for sedation of the ~~minor~~ patient as well as written informed consent of the patient or, as appropriate, parent or legal guardian of the patient.

(2) Oral conscious sedation records shall include baseline vital signs. If obtaining baseline vital signs is prevented by the patient's physical resistance or emotional condition, the reason or reasons must be documented. The records shall also include intermittent quantitative monitoring and recording of oxygen saturation, heart and respiratory rates, blood pressure as appropriate for specific techniques, the name, dose and time of administration of all drugs administered including local and inhalation anesthetics, the length of the procedure, any complications of oral sedation, and a statement of the patient's condition at the time of discharge.

(d) An emergency cart or kit shall be available and readily accessible and shall include the necessary and appropriate drugs and age- and size-appropriate equipment to resuscitate a nonbreathing and unconscious ~~minor~~ patient and provide continuous support while the patient is transported to a medical facility. There must be documentation that all emergency equipment and drugs are checked and maintained on a prudent and regularly scheduled basis. Emergency drugs of the following types shall be available:

(1) ~~Vasopressor~~ Epinephrine

~~(2) Corticosteroid~~

~~(3) Bronchodilator~~

~~(4) Appropriate drug antagonists~~

~~(5) Antihistaminic~~

~~(6) Anticholinergic~~

~~(7) Anticonvulsant~~

~~(8) Oxygen~~

~~(9) Dextrose or other antihypoglycemic~~

NOTE: Authority cited: 1614, Business and Professions Code. Reference: 1647.10, ~~and~~ 1647.16, 1647.22 and 1647.24, Business and Professions Code.



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**APPLICATION FOR COURSE APPROVAL FOR EITHER
ADULT OR MINOR ORAL CONSCIOUS SEDATION**
TYPE OR PRINT LEGIBLY

SECTION 1647.12(c) and 1647.20(c) – BUSINESS AND PROFESSIONS CODE
SECTION 1044.3, Title 16, CALIFORNIA CODE OF REGULATIONS

FOR OFFICE USE ONLY

APPROVED _____

Name of Provider: _____

CA Registered Provider No. _____

Address _____

Contact Person _____ Phone (____) _____

Does this course consist of a minimum of 25 hours of instruction? YES NO

Is this course directed solely toward the administration of oral conscious sedation to ADULTS MINORS (circle ONE only)

**AN OUTLINE OF THE COURSE AND THE INSTRUCTOR'S QUALIFICATIONS MUST BE ATTACHED TO
THIS APPLICATION.**

I certify under the penalty of perjury under the laws of the State of California that the course meets the requirements set forth in the Board's regulations and will be taught to the Board's standards.

Signature

Date

Printed Name

Title



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DOCUMENTATION OF ADULT ORAL CONSCIOUS SEDATION CASES

An applicant for an Oral Conscious Sedation Certificate may document ten cases of oral conscious sedation of patients 13 years or older performed by the applicant in any three-year period ending no later than December 31, 2005. To document, complete this form summarizing the ten cases, and attach legible copies of records of pre-operative evaluation, medical history, monitoring of vital signs throughout the procedure, and condition at discharge. Redact all personal information on the records, and number them as cases 1-10. Submit these documents with the application (Form OCS-3 Rev 03/07). **(Print or Type)**

Name of Applicant _____ Dental License _____

CASE 1 - _____

Patient Sex

Patient Age

Patient Weight

Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

CASE 2 - _____

Patient Sex

Patient Age

Patient Weight

Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

CASE 3 - _____

Patient Sex

Patient Age

Patient Weight

Date of Procedure

Type of Procedure Performed _____ Duration of Sedation _____

Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____

Patient's condition at discharge _____

--Attach legible copies of required records to completed form--

CASE 4 – _____
Patient Sex Patient Age Patient Weight Date of Procedure
Type of Procedure Performed _____ Duration of Sedation _____
Briefly describe method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____
Patient's condition at discharge _____

CASE 5 – _____
Patient Sex Patient Age Patient Weight Date of Procedure
Type of Procedure Performed _____ Duration of Sedation _____
Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____
Patient's condition at discharge _____

CASE 6 – _____
Patient Sex Patient Age Patient Weight Date of Procedure
Type of Procedure Performed _____ Duration of Sedation _____
Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____
Patient's condition at discharge _____

CASE 7 – _____
Patient Sex Patient Age Patient Weight Date of Procedure
Type of Procedure Performed _____ Duration of Sedation _____
Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

How was the patient monitored and by whom? _____
Patient's condition at discharge _____

--Attach legible copies of required records to completed form--

CASE 8 – _____
 Patient Sex Patient Age Patient Weight Date of Procedure
 Type of Procedure Performed _____ Duration of Sedation _____
 Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

 How was the patient monitored and by whom? _____
 Patient's condition at discharge _____

CASE 9 – _____
 Patient Sex Patient Age Patient Weight Date of Procedure
 Type of Procedure Performed _____ Duration of Sedation _____
 Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

 How was the patient monitored and by whom? _____
 Patient's condition at discharge _____

CASE 10 - _____
 Patient Sex Patient Age Patient Weight Date of Procedure
 Type of Procedure Performed _____ Duration of Sedation _____
 Briefly describe the method, amount, and specific oral conscious sedation agent administered _____

 How was the patient monitored and by whom? _____
 Patient's condition at discharge _____

--Attach legible copies of required records to completed form--

Certification – I certify under the penalty of perjury under the laws of the State of California that the information provided in and attached to this form is true and accurate.

 Signature of Applicant

 Date



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 1432 HOWE AVENUE, SUITE 85, SACRAMENTO, CA 95825-3241
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**APPLICATION FOR ADULT ORAL CONSCIOUS
 SEDATION CERTIFICATE**

Sections 1647.18-1647.26 Business and Professions Code;

Non Refundable **FEE: \$200**

(must be enclosed with application)

Section 1021 Title 16 California Code of Regulations

Receipt No. _____ RC _____
 Amount _____ Initials _____
 Certificate No _____
 Issued _____

Name _____

Address of Record (Mail)

Street and Number _____

City _____ ZIP Code _____

Address of Practice if different

Street and Number _____

City _____ ZIP Code _____

Telephone number () _____ FAX _____

Email address _____

Birthdate _____ Dental License Number _____

QUALIFICATION – Indicate under which method listed below you qualify for an oral conscious sedation certificate for adults and attach appropriate documentation.

- ☐ Successful completion of a postgraduate program in oral and maxillofacial surgery approved by the Commission on Dental Accreditation or a comparable organization approved by the Board. Applicant must provide a copy of his or her diploma.
- ☐ Successful completion of a periodontics or general practice residency or advanced education in a general dentistry post-doctoral program accredited by the Commission on Dental Accreditation that meets the didactic and clinical requirements of Section 1044.3 of the Business and Professions Code. Applicant must provide a copy of his or her diploma.
- ☐ Successful completion of a Board-approved educational program on oral medications and sedation. Applicant must provide a copy of his or her certificate of completion.
- ☐ Documentation of 10 successful cases 1647.20(d). Attach Form OCS-4 with copy of treatment records.

Pursuant to Business and Professions Code 1647.22(b), a dentist who administers, or who orders the administration of oral conscious sedation for an adult patient shall be physically present in the treatment facility while the patient is sedated and shall be present until discharge of the patient from the facility.

Provide the addresses of all locations of practice where you order or administer oral conscious sedation to adult patients.

IF NECESSARY, CONTINUE ON BACK OF THIS PAGE.

Certification - I certify under the penalty of perjury under the laws of the State of California that the foregoing is true and correct and I hereby request a certificate to administer or order the administration of adult oral conscious sedation in my office setting(s) as specified by the Dental Practice Act. I understand that falsification or misrepresentation of any item or response on this application or any attachment is grounds for denying my application for a certificate.

Signature of Applicant

INFORMATION COLLECTION AND ACCESS

The information requested herein is mandatory and is maintained by Dental Board of California, 1432 Howe Ave, Suite 85, Sacramento, CA 95825, Executive Officer, in accordance with Business & Professions Code, §1600 et seq. Failure to provide all or any part of the requested information will result in the rejection of the application as incomplete. Each individual has the right to review the personal information maintained by the agency unless the records are exempt from disclosure. Applicants are advised that the names(s) and address(es) submitted will be release to the public upon request and may be posted on the Internet.